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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,826	12/03/2003	Andrew Thomas Forsberg	47563.0017	5521

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EXAMINER

SEVERSON, RYAN J

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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02/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/726,826	Applicant(s) FORSBERG ET AL.	
	Examiner Ryan Severson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-39,41-49,51-73,76 and 77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-39,41-49,51-73,76 and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 May 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 November 2007 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 35, 37, 38, 41-48, 55, and 57-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,662,681).** Nash reference discloses the method substantially as claimed, including providing a device with a carrier tube (102), filament (34), anchor (32), and sealing plug (30) wherein the anchor is seated in a multilevel nest (see figure 1). Nash reference further discloses the device is inserted into a percutaneous incision (see column 6, lines 57-60), the anchor is deployed (see column 6, lines 62-66), withdrawing the device from the incision (see column 7, lines 10-13), and tamping the sealing plug toward the anchor (see column 7, lines 43-51). The nest area of Nash reference is interpreted to be the contact surface where the anchor

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contacts the carrier tube, and an inner surface (the inner lumen surface of carrier tube 102) that is spaced radially inward from the anchor. The tissue puncture is in a blood vessel (see figure 3). The anchor is moved away from and oriented transverse to the carrier tube (see figure 2).

4. **Claims 37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonutti (5,814,073).** Bonutti reference discloses the method substantially as claimed, including providing a gap between a carrier tube (54) and the anchor (22) by creating a multi-level nest in the carrier tube (see figure 10). The nest of Bonutti reference is interpreted to be multi-level because it has a contact surface (distal end of 56) and a non-contact surface (the inner lumen surface of tube 54) that is disposed radially inward of the contact surface. The introducer sheath acts as a one-way valve to prevent the anchor from passing back into the sheath because it has a tip with resilient members. The resilient members close upon passage of the anchor there through.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 36, 49, 51-54, 56, 63-66, 71-73, 76, 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (5,662,681) in view of Bonutti (5,814,073).** Nash reference does not disclose sliding a tip of an insertion sheath into a gap formed between the anchor and the nest during anchor deployment. Attention is

drawn to Bonutti reference, which teaches an introducer sheath (30) may have a resilient tips (see column 6, lines 53-56) which can move from open (when the anchor is being passed there through) to closed (upon passage of the anchor through the tip of the introducer sheath) positions to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the introducer sheath with resilient tips of Bonutti reference with the closure device of Nash reference to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment.

7. Furthermore, Nash reference states the closure device may be used with any typical introducer sheath (see column 4, lines 24-29). The tip of the insertion sheath would slide into a gap between the anchor and the nest because the tip of the sheath is resilient. The resiliency will cause the tips to conform to the shape it is compressed around, thereby filling the gap of Nash reference when that point is reached.

8. **Claims 67-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (5,282,827).** Kensey reference discloses the method substantially as claimed, including providing a device with a carrier tube (102), an anchor (32', see figures 34 and 35), and a sealing plug (30). The anchor is indented because of the area between the raised cap portions (32b) and the center of the anchor (see figure 35). The indent will cause a gap between the anchor and the carrier tube. The tissue puncture is in a blood vessel (see figures 16-18). The device includes a filament (34) that couples the sealing plug and the anchor together (see figures 2 and 3). The anchor is moved

away from and oriented transverse to the carrier tube (see figure 22). However, Kensey reference does not disclose sliding a tip of an insertion sheath into a gap formed between the anchor and the nest during anchor deployment. Attention is drawn to Bonutti reference, which teaches an introducer sheath (30) may have a resilient tips (see column 6, lines 53-56) which can move from open (when the anchor is being passed there through) to closed (upon passage of the anchor through the tip of the introducer sheath) positions to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the introducer sheath with resilient tips of Bonutti reference with the closure device of Kensey reference to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment.

Response to Arguments

9. Applicant's arguments filed 26 November 2007 have been fully considered but they are not persuasive. Examiner notes that it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961). Since applicant merely claims providing the device with the multi-level nest, and doesn't claim how that structure is used in a method in a manipulative sense, the arguments that the prior art does not disclose the multi-level nest as claimed are not persuasive because the prior art references do perform the method steps substantially as claimed.

Conclusion

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571)272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731